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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,672	01/14/2000	Jiangchun Xu	210121.42711C11	8685

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/483,672	XU ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65,74,75 and 77-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *65 and 74* is/are allowed.

6)☒ Claim(s) *75 and 77-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20040303*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/15/03 has been entered. Claims 65, 74-74 and 77-79 are pending.

All rejections and objections not repeated below are hereby withdrawn in view of the amendment filed 4/15/03. An action on the merits of claims 65, 74-74 and 77-79, as they read on elected SEQ ID NO: 525, follows.

Information Disclosure Statement

In the response filed 4/15/03, applicant requested confirmation of receipt of references labeled BL, BM, and DJ in the IDS filed 11/2/03. Applicant stated that these references were supplied with the response filed March 6, 2002. While the transmittal page filed with the response of 3/6/01 indicates that references were filed, there is no record of these papers anywhere in the PTO's file. In addition, it is noted that the references were not considered as the citations appeared to be incorrect. The examiner has again searched the various NCBI databases and has not found any NCBI accession numbers corresponding to those in the IDS of 11/2/03. The examiner apologizes for the inconvenience, and requests that copies of the references in question be refiled. In addition, the examiner recommends that applicant review the citations on

the IDS of 11/2/03 to confirm that the citations indeed match the references. If not, then applicant is reminded that a new IDS correctly listing these references must be filed in order for those references to be considered and made of record. The filing date for the references will be that of the new IDS.

Drawings

Clean copies of corrected drawings were filed with the response of 4/14/03. The examiner thanks the applicants and attorney for their forbearance and prompt response. The new drawings are acceptable to the examiner.

Priority

Applicant is reminded that priority for claims reciting SEQ ID NO: 525 is granted only to 11/12/99.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 75 and 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over GIMENO et al. (US 5,955,306) in view of HAUSER et al. (US 5,776,468).

Claim 75 recites a composition comprising an immunostimulant and an isolated polypeptide comprising at least residues 112-120 of SEQ ID NO: 525, wherein the immunostimulant induces a predominantly Th1-type response. Claim 77 limits the immunostimulant to monophosphoryl lipid A (MPL), a CpG-containing oligonucleotide, a saponins, or a combination of these. Claim 78 limits the immunostimulant to be 3D-MPL, QS21, or a combination.

GIMENO teaches a protein represented by his SEQ ID NO: 31 (col's 73-76), which is 97.6% identical to instant SEQ ID NO: 525, is immunogenic and may be formulated in a composition with an adjuvant or physiologically acceptable carrier, as set forth above. Residues 82-90 of GIMENO's sequence are identical to residues 112-120 of instant SEQ ID NO: 525. GIMENO does not teach an immunostimulant which induces a Type I response.

HAUSER teaches an improved adjuvant, small MPL, which preferentially induces IgG_{2a}, and induces a Type I response (col. 18, lines 5-30 and col. 28, lines 1-10). HAUSER further teaches that his small adjuvant may contain MPL and QS21 (col. 3,

line 62-col. 4, line 13). HAUSER teaches that his adjuvant may be combined with any antigen (col. 1, lines 37-41 and col. 25, claims 1-5).

It would have been obvious to one skilled in the art at the time of invention to have used HAUSER's MPL and QS21 as the adjuvant(s) in the composition of GIMENO where the motivation would have been to use an improved adjuvant for production of antibodies, as suggested by HAUSER's teachings that MPL is an improved adjuvant compared to other known adjuvants. One skilled in the art would reasonably have expected success in combining HAUSER's MPL and/or QS21 with GIMENO's protein because GIMENO teaches that his protein is antigenic and may be combined with adjuvants and HAUSER teaches that his MPL and QS21 may be combined with any antigen.

Applicant's arguments filed 4/15/03 have been fully considered but they are not persuasive. In response to applicant's arguments that GIMENO does not teach the polypeptides "capable of stimulating a human T-cell response", it is noted that claim 75 does not recite such a limitation. The polypeptide of clam 75 is limited to comprise a T-cell epitope, specifically amino acids 112-120 of SEQ ID NO: 525. As set forth above, GIMENO's peptide comprise amino acids identical to residues 112-120 of instant SEQ ID NO: 525, and thus meets the recited limitations. It is noted that the *immunostimulant* of claim 75 is limited to induce a predominantly Th1-type of response. As the rejection is made over a combination of references wherein HAUSER teaches an adjuvant (immunostimulant) which induces a Type-1 response, the examiner maintains that the references make obvious the claimed composition. In response to applicant's argument

that the prior art does not teach use of GIMENO's protein to elicit a T-cell response, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, a motivation to use the known adjuvants of HAUSER as the adjuvant in the composition of GIMENO is to use an improved adjuvant, as taught by the prior art of HAUSER, and set forth above.

Claims 75 and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over GIMENO et al. (US 5,955,306) in view of CABEZON SILVA et al. (WO 9701640).

Claim 75 recites a composition comprising an immunostimulant and an isolated polypeptide comprising at least residues 112-120 of SEQ ID NO: 525, wherein the immunostimulant induces a predominantly Th1-type response. Claim 77 limits the immunostimulant to monophosphoryl lipid A (MPL), a CpG-containing oligonucleotide, a saponins, or a combination of these. Claim 78 limits the immunostimulant to be 3D-

MPL, QS21, or a combination. Claim 79 limits the immunostimulant to comprise 3D-MPL, QS21 and tocopherol in an oil-in-water emulsion.

GIMENO teaches a protein represented by his SEQ ID NO: 31 (col's 73-76), which is 97.6% identical to instant SEQ ID NO: 525, is immunogenic and may be formulated in a composition with an adjuvant or physiologically acceptable carrier, as set forth above. Residues 82-90 of GIMENO's sequence are identical to residues 112-120 of instant SEQ ID NO: 525. GIMENO does not teach an immunostimulant which induces a Type I response nor the specific immunostimulants recited in the claims.

CABEZON SILVA teaches an adjuvant comprising QS21 and 3D-MPL in an oil-in-water emulsion comprising tocopherol (p. 6, lines 5-12) , teaches that this adjuvant elicits a TH1 response (p. 5, lines 16-19), and teaches that the combination of QSL and 3D-MPL in an oil-in-water emulsion is an improvement over other adjuvants because it induces a wider spectrum of immune responses to an antigen (p. 5, lines 28-34).

It would have been obvious to one of ordinary skill in the art at the time of invention to have used the QSL/3D-MPL/tocopherol oil-in-water emulsion of CABEZON SILVA as the adjuvant in the composition of GIMANO where the motivation would have been to elicit a better response to the polypeptide antigen, as suggested by the teaching of CABEZON SILVA that her adjuvant elicits a wider spectrum of response than other adjuvants.

Applicant's arguments filed 4/15/03 have been fully considered but they are not persuasive. Applicant argues that the same reasoning as that applied above may also be applied to the combination of GIMENO and CABEZON SILVA. The examiner

maintains that GIMENO's protein meets the limitations for the "isolated polypeptide" for the same reasons as those set forth above. The instant rejection is made over a combination of references wherein CABEZON SILVA teaches an adjuvant (immunostimulant) which induces a Type-1 response, therefore the examiner also maintains that the references make obvious the claimed composition. Specifically, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, a motivation to use the known adjuvants of CABEZON SILVA as the adjuvant in the composition of GIMENO is to use an improved adjuvant, as taught by the prior art of CABEZON SILVA, and set forth above.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: The prior art neither teaches nor fairly suggests an isolated polypeptide comprising SEQ ID NO: 525, as recited in claims 65 and 74.

It is noted that claims 4 and 5 of US Patent 6,465,611 recite compositions comprising an adjuvant and a peptide which is identical to residues 112-120 of instant SEQ ID NO: 525, and thus encompasses as least part of the scope of instant claim 75. However, as the instant claims recite a different SEQ ID NO than is recited in claims of the US patent, and the recitation of different SEQ ID NO's is due to restriction practice, the claims do not represent double patenting.

Conclusion

Claims 75 and 77-79 are rejected; claims 65 and 74 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

mam